JUL - 3 2000

K001235

510(K) SUMMARY

Submitted by:

Ralph H. Larsen
Manager, Regulatory Affairs
Alcon Research Ltd..
6201 South Freeway
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(817) 551-4702 (Phone)
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Device Name:

Common Name: Contact Lens Cleaning Solution

Proprietary Name: OPTI-FREE® SUPRACLENS® Daily Protein Remover / RGP Multi-Purpose Disinfecting Solution ID 100136

Indications for Use:

OPTI-FREE® SUPRACLENS® Daily Protein Remover

OPTI-FREE® SUPRACLENS® Daily Protein Remover is indicated for use with clear and tinted, daily wear and extended wear soft (hydrophilic) contact lenses or rigid gas permeable (silicone acrylate fluorosilicone acrylate) lenses to simultaneously enzymatically clean them while they are being disinfected (soaked) in, OPTI-FREE Rinsing, Disinfecting and Storage Solution, OPTI-ONE Multi-Purpose Solution, OPTI-FREE EXPRESS Multi-Purpose Solution or conditioned in OPTI-SOAK Conditioning Solution or RGP Multi-Purpose Disinfecting Solution ID 100136. **Use as recommended by your eye care practitioner**.

RGP Multi-Purpose Disinfecting Solution ID 100136

RGP Multi-Purpose Disinfecting Solution ID 100136 is for the cleaning, rinsing, disinfection and conditioning of fluorosilicone acrylate and silicone acrylate rigid gas permeable contact lenses.

RGP Multi-Purpose Disinfecting Solution ID 100136 can also be used as a diluent for OPTI-FREE® SUPRACLENS® Daily Protein Remover.

Description:

OPTI-FREE® SUPRACLENS® Daily Protein Remover

OPTI-FREE® SUPRACLENS® Daily Protein Remover is a preservative-free solution which contains propylene glycol, sodium borate, and highly purified porcine pancreatin enzymes as the active cleaning ingredient.

RGP Multi-Purpose Disinfecting Solution ID 100136

RGP Multi-Purpose Disinfecting Solution ID 100136 is a sterile, aqueous solution buffered to approximate the pH and tonicity of the eye. It contains AL12355™ (hydroxypropyl guar), a unique wetting/conditioning polymer system, polyethylene glycol, tetronic, boric acid, propylene glycol and is preserved with POLYQUAD® (polyquaternium-1) 0.0011% and edetate disodium 0.10%.

Substantial Equivalence:

This product is substantially equivalent, in terms of its actions and indications for use, to the Alcon OPTI-FREE® SUPRACLENS® Daily Protein Remover (PMA 82002/S18)/OPTI-SOAK™ Conditioning Solution (PMA 830071/S08) combination. The OPTI-FREE SUPRACLENS Daily Protein Remover/RGP Multi-Purpose Disinfecting Solution ID 100136 combination meets the guidelines set forth in FDA's May 1, 1997 Guidance for Industry; Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products.

Safety and Effectiveness:

A. Non-Clinical Data

Microbiological Studies

The combination OPTI-FREE SUPRACLENS Daily Protein Remover/RGP Multi-Purpose Disinfecting Solution ID 100136 was evaluated for disinfection efficacy using the FDA guidelines for contact lens solutions. The results demonstrate that the antimicrobial activity of RGP Multi-Purpose Disinfecting Solution ID 100136 is not reduced by the addition of OPTI-FREE SUPRACLENS Daily Protein Remover.

The testing involved three lots of the test sample. The solutions were tested using a method based on the FDA and ISO/DIS Stand Alone test methods. The testing was conducted using the following challenge organisms: *Staphylococcus aureus* ATCC *6538, Pseudomonas aeruginosa* ATCC 9027, *Serratia marcescens* ATCC 13880, *Candida albicans* ATCC 10231, and *Fusarium solani* ATCC 36031. Polypropylene tubes were used to contain the test and control samples. The results of testing the three lots of sample demonstrated that they meet the primary criteria of the FDA/ISO standards for disinfection efficacy (Stand Alone Test). RGP Multi-Purpose Solution ID 100136 is effectively preserved as demonstrated by the FDA Rechallenge Preservative Effectiveness Standards applied to multi-dose preserved contact lens care products.

Preclinical

The preclinical safety evaluation conducted concludes that OPTI-FREE SUPRACLENS Daily Protein Remover when used daily with RGP Multi-Purpose Disinfecting Solution ID 100136 and RGP contact lenses in rabbits produced ocular effects that were generally confined to the conjunctiva, minimal in nature and were judged to be of no clinical significance. Based on the results of this study and other preclinical studies, OPTI-FREE SUPRACLENS Daily Protein Remover is safe for its intended use with RGP Multi-Purpose Disinfecting Solution ID 100136 in the simultaneous cleaning and disinfection of rigid gas permeable contact lenses (silicone acrylate and fluorosilicone acrylate) and similar contact lens polymers and should not present an ocular hazard to the consumer

under the recommended lens treatment regimen or under conditions of accidental or intentional misuse.

Compatibility/Cleaning Efficacy

Product compatibility with rigid gas permeable contact lenses and the product's ability to clean laboratory deposited lens were evaluated. These studies demonstrate the compatibility and cleaning efficacy of OPTI-FREE® SUPRACLENS® Daily Protein Remover dissolved in RGP Multi-Purpose Disinfecting Solution ID 100136.

Proteolytic Activity Study

The proteolytic activity of OPTI-FREE SUPRACLENS Daily Protein Remover in RGP Multi-Purpose Disinfecting Solution ID 100136 was determined. Results were consistent with the expected theoretical value.

B. Clinical

A clinical study was conducted and demonstrated that the OPTI-FREE SUPRACLENS Daily Protein Remover / RGP Multi-Purpose Disinfecting Solution ID 100136 regimen is safe and effective for the daily enzymatic cleaning and conditioning/disinfection of silicone acrylate and fluorosilicone acrylate rigid gas permeable contact lenses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2000

Mr. Ralph H. Larsen
Manager
Regulatory Affairs
Alcon
6201 South Freeway
Fort Worth, Texas 76134-2099

Re: K001235
Trade Name: OPTI-FREE® SUPRACLENS® Daily Protein Remover/RGP Multi-Purpose Disinfecting Solution ID 100136
Regulatory Class: II
Product Code: 86 MRC
Dated: April 14, 2000
Received: April 17, 2000

Dear Mr. Larsen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K001235

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001235

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)